EXHIBIT 1

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IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
EASTERN DIVISION

EDWARD PEÑA and BRANDON MILLER, individually and on behalf of others similarly situated,

~~Plaintiff~~Plaintiffs,

v.

INTERNATIONAL MEDICAL DEVICES, INC., MENOVA INTERNATIONAL, INC., GESIVA MEDICAL, LLC, JAMES J. ELIST M. D., a Medical Corporation, and Dr. James ELIST,

Defendants.

CASE NO. 2:22-cv-03391-SSS (PLAx)

~~PLAINTIFF'S SECOND AMENDED CLASS ACTION COMPLAINT~~

PLAINTIFFS' THIRD AMENDED CLASS ACTION COMPLAINT

~~Plaintiff~~Plaintiffs Edward Peña ~~files~~and Brandon Miller file this ~~Original~~Third Amended Class Action Complaint against Defendants International Medical Devices, Inc. ("IMD"), Menova International, Inc. ("Menova"), Gesiva Medical, LLC ("Gesiva"), James J. Elist, M.D., a Medical Corporation, and Dr. James Elist and in support of ~~his~~their claims ~~alleges~~allege as follows.

I. INTRODUCTION

1. Defendants have jointly developed and marketed the "Penuma" device, a silicone penile implant, as a penis enlargement device. Since at least January 2017, Defendants have engaged in a systematic, coordinated campaign to market Penuma for cosmetic penis enlargement. Their websites and advertisements target men who have healthy, normal bodies but simply want larger penises.

2. Dr. James J. Elist has also developed a surgical procedure for implanting the device. He has performed thousands of these procedures, handling patient consults at his clinic in Beverly Hills and performing penile implant surgeries in his operating room at the Beverly Hills South Pacific Surgery Center. Defendants falsely and misleadingly tout the device and procedure as "FDA-cleared," giving reasonable consumers the false impression that the U.S. Food and Drug Administration ("FDA") has determined that Penuma is safe and effective for cosmetic penis enlargement procedures in men with healthy, normal bodies.

3. Unbeknownst to the men who undergo these procedures, however, the FDA has never tested Penuma or determined that it is ~~not~~ safe and effective~~— nor is it FDA~~. Instead, the FDA granted Penuma "premarket clearance" for sale only under a cursory process that the FDA's own regulations state "does not in any way denote official approval of the device." 21 C.F.R. § 807.97. Indeed, up until May 13, 2022, Penuma was not even FDA cleared— for cosmetic penile enlargement. Instead, Penuma ~~is~~was FDA-cleared only "***for use in the cosmetic correction of soft***

tissue deformities." While Penuma applied for and received—again, without undergoing any of the safety and effectiveness testing required for FDA approval—a new clearance for "cosmetic augmentation of the penis" in 2022, the FDA included a cautionary reference in granting the clearance to 21 C.F.R. § 807.97's regulation that "any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding." *Id.*

3.4. Worse, implantation of the Penuma device not only does not usually result in any lengthening of the penis, it frequently causes scarring, resulting in the penis becoming shorter. In addition, contrary to Defendants' misrepresentations that the procedure is "permanent" but "reversible," the procedure frequently leads to infections and complications that require removal of the device, which, in turn, causes permanent damage to the penis. Defendants knew these facts at least by 2015, but nevertheless continued to market Penuma as "the first FDA-cleared penile implant for cosmetic enhancement" and to urge consumers with healthy, normal penises to purchase the Penuma device and procedure to "enhance and enlarge the length, girth, and size of your penis."

4.5. Defendants profited substantially from these misrepresentations, selling the Penuma device and procedure to thousands of men at a cost of $15,000–$20,000 each. PlaintiffPlaintiffs accordingly bringsbring this action to recover damages and restitution on behalf of similarly situated consumers and to enjoin Defendants from continuing to falsely advertise and market Penuma as a safe and effective FDA-cleared procedure for cosmetic enhancement of penis size in men with healthy penises.

II. PARTIES

5.6. Plaintiff Edward Peña is a resident of Hidalgo County, Texas.

7. Plaintiff Brandon Miller is a resident of Fresno County, California.

~~6.~~8. Defendant International Medical Devices, Inc. ("IMD") is a California corporation located at 717 N. Maple Drive, Beverly Hills, CA 90210, in Los Angeles County. It may be served through its registered agent, Jonathan Elist, at the same address.

~~7.~~9. Defendant Menova International, Inc., ("Menova") is a California corporation located at 8500 Wilshire Blvd., Suite 707, Beverly Hills, CA 90211, in Los Angeles County. It may be served through its registered agent, James Elist, at the same address.

~~8.~~10. Defendant Gesiva Medical, LLC is a Minnesota limited liability corporation headquartered at 6385 Old Shady Oak Road, Suite 250, Eden Prairie, MN 55344. It may be served through its registered agent, Thomas A. Hopper, at the same address.

~~9.~~11. Defendant James J. Elist, M.D., a Medical Corporation, is a California corporation headquartered at 8500 Wilshire Blvd., Suite 707, Beverly Hills, CA 90211. It may be served through its registered agent, James J. Elist, at the same address.

~~10.~~12. Defendant Dr. James Elist is an individual residing in Beverly Hills, California. Dr. Elist may be served at 8500 Wilshire Blvd., Suite 707, Beverly Hills, CA 90211.

III. JURISDICTION AND VENUE

~~11.~~13. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action involving over 100 class members in which at least one member of the class is a citizen of a State different from at least one Defendant and the matter in controversy exceeds $5,000,000, exclusive of ~~interests~~interest and costs.

~~12.~~14. Defendants IMD, Menova, James J. Elist, M.D., a Medical Corporation, and Dr. Elist are subject to general personal jurisdiction in California because IMD, Menova, and James J. Elist, M.D., a Medical Corporation are incorporated in California and maintain their principal places of business in California, and Dr. Elist is a California resident.

~~13.~~15. The Court also has specific personal jurisdiction over all Defendants because Defendants purposefully availed themselves of the privilege of doing business in California, and this action arises out of and relates to Defendants' California business activities.

~~14.~~16. Venue is proper in this district under 28 U.S.C. § 1391(b), because a substantial part of the events or omissions giving rise to ~~Plaintiff's~~Plaintiffs' claims occurred in Los Angeles County.

~~15.~~17. In addition, venue is also proper in this district pursuant to 28 U.S.C. § 1391(a). Defendants are deemed to reside in this district because their contacts with this district would be sufficient to subject them to personal jurisdiction if this district were a separate state.

IV. JOINT ENTERPRISE LIABILITY

~~16.~~18. Defendants shared a common plan or design for illegally marketing the Penuma device and procedure for cosmetic enlargement of normal penises.

~~17.~~19. Each Defendant had knowledge of and agreed to market Penuma for the cosmetic enlargement of normal penises.

~~18.~~20. Defendants acted as a joint enterprise with regard to all of the actions alleged in this Complaint.

~~19.~~21. Whenever this Complaint makes reference to any act of Defendants, the allegations refer to each of the Defendants, acting individually, and also to all of the Defendants acting jointly.

~~20.~~22. All acts of each of the Defendants were ratified and adopted by each of their Co-Defendants.

V. STATEMENT OF FACTS

A. Implant of Penuma Device for Plaintiff Edward Peña

~~21.~~23. Before undergoing the Penuma implantation procedure, Plaintiff Edward Peña had a normal, healthy penis. He had no soft tissue deformity of the penis, nor any urological problems of any kind.

~~22.~~24. While browsing the Internet, Mr. Peña saw advertisements for the Penuma device and procedure, including Dr. Elist's website. Defendants made the marketing decisions that led to these advertisements in Los Angeles, California.

~~23.~~25. Having read Defendants' advertisements, Mr. Peña reasonably believed that the Penuma device was safe and effective for men like him who had normal penises, but simply wanted their penises to be larger. He further reasonably believed, based on the misrepresentations in Defendants' advertisements, that the Penuma device had been approved by the FDA, and this belief gave him a sense of comfort that the device was safe and effective. Had Mr. Peña known that Penuma had not in fact been approved or cleared by the FDA for cosmetic penile enlargement in men with normal penises and/or that it was not safe and effective for men with normal, healthy penises, he would not have purchased the Penuma device or procedure.

~~24.~~26. Mr. Peña also reasonably believed, based on misrepresentations in Defendants' advertisements, that the Penuma procedure was permanent and completely reversible and that there would be no adverse consequences from removal of the device. Had Mr. Peña known that the Penuma implantation procedure was not permanent and could not be reversed without causing permanent damage to the penis, he would not have purchased the Penuma device or procedure.

~~25.~~27. Mr. Peña also reasonably believed, based on misrepresentations in Defendants' advertisements, that the Penuma procedure would result in a natural looking penis. Had Mr. Peña known that the Penuma procedure often results in abnormal and deformed-looking penises, he would not have purchased the Penuma device or procedure.

~~26.~~28. Mr. Peña contacted Dr. Elist and scheduled an appointment with him for October of 2020. Dr. Elist consulted with Mr. Peña for approximately 15 minutes. Mr. Peña also met with three or four other employees of Dr. Elist and filled out a questionnaire. At no point did Dr. Elist or his employees inform Mr. Peña that Penuma was not safe and effective or not FDA cleared for cosmetic enlargement of normal penises. One or two days later, Dr. Elist performed surgery to implant the Penuma device in Mr. Peña's body.

~~27.~~29. Mr. Peña paid $14,500 to Dr. James Elist for the device and surgery.

~~28.~~30. Following the surgery, Mr. Peña's penis did not look or feel natural. Instead, he had no feeling on the top of the shaft and pain on bottom of the shaft. Two corners of the implant began sticking out in a manner that was not aesthetically pleasing. Mr. Peña suffered pain during intercourse and especially severe pain after intercourse. The implant eventually punctured the skin and poked out through a small hole, through which fluid discharged. Mr. Peña could not sleep on his back or his stomach. He woke up multiple times in the middle of the night with painful erections, making it extremely difficult for him to sleep for at least 3 months. Mr. Peña could not even bend down to tie his shoe without pain.

~~29.~~31. Mr. Peña then decided to have the Penuma device removed. He had the device removed by Dr. Bryan Kansas, a reconstructive urological surgeon in Austin. Following the removal, Mr. Peña has continued to suffer complications, including

retraction, loss of sensation, and scarring. These complications have caused Mr. Peña significant pain and mental anguish.

30.32. Mr. Peña's experience led him to conclude that the Penuma device and procedure have no value and are not safe or effective for healthy men with normal penises, many of whom had been and would continue to be misled by Defendants' misrepresentations to pay thousands of dollars for a device and surgery that have no value. He further understood that many of these men were unlikely to be able to secure legal representation on their own to pursue their claims against Defendants. He therefore files this action on his own behalf and on behalf of similarly situated persons.

B. Implant of Penuma Devices into Plaintiff Brandon Miller

33. Before undergoing the Penuma implantation procedure, Plaintiff Brandon Miller had a normal, healthy penis. He had no soft tissue deformity of the penis, nor any urological problems of any kind.

34. While browsing the Internet, Mr. Miller saw advertisements for the Penuma device and procedure, including Dr. Elist's website. Defendants made the marketing decisions that led to these advertisements in Los Angeles, California.

35. Having read Defendants' advertisements, Mr. Miller reasonably believed that the Penuma device was safe and effective for men like him who had normal penises, but simply wanted their penises to be larger. He further reasonably believed, based on the misrepresentations in Defendants' advertisements, that the Penuma device was had been approved by the FDA, and this belief gave him a sense of comfort that the device was safe and effective. Had Mr. Miller known that Penuma had not in fact been approved or cleared by the FDA for cosmetic penile enlargement in men with normal penises and/or that it was not safe and effective for men with

normal, healthy penises, he would not have purchased the Penuma device or procedure.

36. Mr. Miller also reasonably believed, based on misrepresentations in Defendants' advertisements, that the Penuma procedure was permanent and completely reversible and that there would be no adverse consequences from removal of the device. Had Mr. Miller known that the Penuma implantation procedure was not permanent and could not be reversed without causing permanent damage to the penis, he would not have purchased the Penuma device or procedure.

37. Mr. Miller also reasonably believed, based on misrepresentations in Defendants' advertisements, that the Penuma procedure would result in a natural looking penis. Had Mr. Miller known that the Penuma procedure often results in abnormal and deformed-looking penises, he would not have purchased the Penuma device or procedure.

38. Mr. Miller contacted Dr. Elist and scheduled an office visit in April 2019 to learn about the Penuma device. Mr. Miller met with a sales representative for Defendants who assured him of the safety and normal appearance and function of the Penuma device.

39. In November 2019, Dr. Elist performed the first Penuma implant surgery on Mr. Miller. Dr. Elist consulted with Mr. Miller briefly before the procedure. At no point did Dr. Elist or his employees inform Mr. Miller that Penuma was not safe and effective or not FDA cleared for cosmetic enlargement of normal penises.

40. Mr. Miller paid $14,000 to Dr. James Elist for the device and surgery.

41. Following the surgery, Mr. Miller's penis did not look or feel natural. Instead, he had a crease on both sides of his penis that was not aesthetically pleasing.

42. Mr. Miller followed all post-operative instructions from Dr. Elist, and after six weeks, he was cleared by Dr. Elist's office to resume all normal activities.

43. Due to continued complications and the abnormal appearance of his penis, Mr. Miller returned to Dr. Elist for a second implantation surgery in November 2020. Dr. Elist charged Mr. Miller an additional $7,000 for this second surgery.

44. After the second implant surgery, Mr. Miller developed a hole in his penis through which fluid leaked. Dr. Elist first prescribed a nitroglycerin ointment to help the hole heal. The ointment did not remedy the problem.

45. In March 2021, Mr. Miller returned to Dr. Elist for a third Penuma surgery to address the leaking fluid through the hole in his penis. Before this third surgery, Dr. Elist indicated that the plan was to replace or remove the implant. Dr. Elist then removed the implant and said that he did not think that Mr. Miller's penis was in a condition to receive another implant.

46. During Dr. Elist's course of treatment, he administered Kenalog injections to Mr. Miller's penis in an attempt to break down the scarring and restore some of the length to his penis that was lost due to the Penuma implant and its removal. Despite multiple administrations by Dr. Elist's clinic, the Kenalog injections did not reduce the scarring or restore length to Mr. Miller's penis.

47. Following the removal of the Penuma, Mr. Miller has continued to suffer complications, including retraction, loss of sensation, and scarring. These complications have caused Mr. Miller significant pain and mental anguish.

48. Mr. Miller's experience led him to conclude that the Penuma device and procedure have no value and are not safe or effective for healthy men with normal penises, many of whom had been and would continue to be misled by Defendants' misrepresentations to pay thousands of dollars for a device and surgery that have no value. He further understood that many of these men were unlikely to be able to secure legal representation on their own to pursue their claims against Defendants.

He therefore files this action on his own behalf and on behalf of similarly situated persons.

VI. CLASS ALLEGATIONS

A. Defendants jointly developed and marketed the Penuma device and implantation procedure.

~~31.~~49. Promoting himself as the "Thomas Edison of penis surgeries," Dr. Elist received a patent on the device that was later to be named "Penuma" in 2002. He submitted an application for FDA clearance in 2004, analogizing the device to a silicone implant used for reconstructive surgery of the ear, nose, and throat. In this and all subsequent FDA clearance applications up through the clearance granted on January 23, 2019, Defendants specifically limited the intended use for the device to the "correction of soft-tissue deformities."

50. On May 9, 2022, after a Class action making allegations similar to this one had been filed in the Eastern District of California, Defendants applied for a new premarket clearance from the FDA. The new clearance application prepared by Defendants stated under "Indications for Use" that "the device provides cosmetic augmentation of the penis and is intended for aesthetic purposes." On May 13, 2022, without performing any testing for safety or effectiveness, the FDA issued a standard "premarket clearance" letter stating that, because Penuma was "substantially equivalent" to "devices marketed in interstate commerce prior to May 28, 1976" Defendants were permitted to market the device "subject to the general controls provisions of the [Federal Food, Drug, and Cosmetic Act]."

51. The 2022 premarket clearance letter cautioned:

> Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other

> requirements of the [Federal Food, Drug, and Cosmetic Act].

The letter further referred to the FDA's regulation entitled "Misbranding by reference to premarket notification," 21 C.F.R. 807.97, which prohibits representing premarket clearance as "in any way denot[ing] official approval of the device":

> Submission of a premarket notification in accordance with this subpart, and a subsequent determination by the Commissioner that the device intended for introduction into commercial distribution is substantially equivalent to a device in commercial distribution before May 28, 1976, or is substantially equivalent to a device introduced into commercial distribution after May 28, 1976, that has subsequently been reclassified into class I or II, ***does not in any way denote official approval of the device***. Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations ***is misleading and constitutes misbranding.***

21 C.F.R. § 807.97

~~32.~~52. Beginning in 2004, Dr. Elist created National Medical Devices, Inc. ("NMD")—the predecessor of Defendant IMD—to manufacture the device and serve as its exclusive distributor. Through NMD, Dr. Elist began marketing the device and offering surgical services to implant the device from his clinic in Beverly Hills.

~~33.~~53. In 2013, Dr. Elist renamed NMD "International Medical Devices, Inc." Dr. Elist is the President of IMD and owns 100% of IMD. His son, Jonathan Elist, is IMD's chief executive officer.

~~34.~~54. Dr. Elist subsequently created Menova to hold the intellectual property associated with his silicone penile implant device. On January 10, 2016, Menova applied for trademark registration for the "Penuma" mark with the United States Patent and Trademark Office ("USPTO"). On September 20, 2016, the USPTO issued a trademark for "Penuma." Since that time, Menova has owned the Penuma trademark and all intellectual property rights associated with the device. Dr. Elist is the president of Menova and owns 100% of Menova.

~~35.~~55. In May 2017, IMD entered into an agreement with Gesiva for the distribution of Penuma devices. Menova and Dr. Elist have authorized IMD and Gesiva to contract with approximately 12 urologists around the United States to perform hundreds of Penuma implantation procedures and use the Penuma trademark. Dr. Elist personally trains all urologists authorized to implant the Penuma.

~~36.~~56. Penuma's advertising claims that the device will make patients' penises longer. That is false. There is no evidence that the Penuma device makes patients' non-erect penises longer. Worse, Penuma's design results in patients' erect penises becoming *shorter* in most cases and in many cases disfigured. Defendants have known about these complications for at least over half a decade. In a 2015 post titled "My Elist Implant Experience," a former patient detailed his effort at seeking a refund from Dr. Elist after his "erect length" shrank between 1–1.5" post-surgery. He received no refund. Similar patient complaints were posted on the internet during the same timeframe. Instead of correcting his false and misleading claims, Dr. Elist responded to these complaints with cease-and-desist letters. Patient concerns

regarding the Penuma were echoed by practitioners and academics as well. For example, a 2018 article published in the Journal of Sexual Medicine titled "Complications of Genital Enlargement Surgery" identified "major penile shortening and disabling curvature" as Penuma complications.

~~37.~~57. Instead of disclosing these material risks, Defendants directed consumers to a self-authored, and self-serving, Elist study from 2018 ("*A Single-Surgeon Retrospective and Preliminary Evaluation of the Safety and Effectiveness of the Penuma Silicone Sleeve Implant for Elective Cosmetic Correction of the Flaccid Penis*") throughout their marketing. This study, however, was not conducted according to scientific standards, and its unreliability has been noted in the medical literature. Drs. Kapadia, Olson, and Furr, among others, concluded that Dr. Elist's study failed to consider "long-term sequelae of such adverse events and implant removal, such as penile shortening, fibrosis, and sexual dysfunction."[1] Because "the infection and explantation rate may be higher than reported in this retrospective study due to incomplete cohort response to surveys,"[2] several urologists have cautioned that "rigorous investigation with accurate reporting of complications should be mandated before more men take on the physical, mental, and significant financial burden associated with subcutaneous silicone penile implants."[3] Defendants' marketing failed to disclose and actively concealed these facts from consumers.

[1] Hehemann, *Penile Girth Enlargement Strategies: What's the Evidence?*, 7 SEXUAL MEDICINE REVIEW 535–547, 542 (2019).

[2] Olson, *Management of infected Penuma implant: Case Report*, 6 J. CASE REPORTS AND IMAGES IN UROLOGY 1–3, 2 (2021).

[3] Hehemann at 543.

B. Penuma ~~has been~~was FDA-cleared only for cosmetic correction of deformities up until May 13, 2022.

~~38.~~58. Because Penuma is a medical device, it is subject to the Medical Device Amendments of 1976 ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"). The MDA established three "classes" of medical devices: Class I, II, and III. "The three classes are based on the degree of control necessary to assure that the various types of devices are safe and effective."[4] A post-1976 medical device is automatically placed into Class III and is subject to premarket approval ("PMA") requirements, including the FDA's independent "scientific review to ensure the safety and effectiveness" of the device. The PMA process is highly rigorous, requiring manufacturers to submit detailed information regarding the safety and effectiveness of their devices. The FDA spends an average of 1,200 hours reviewing each submission.

~~39.~~59. Devices that were on the market before the MDA was enacted, however, are grandfathered in and are not required to go through the PMA process. Manufacturers seeking a less stringent review can thus avoid the FDA's thorough, scientific PMA process by showing that their devices are "substantially equivalent" to devices that were already on the market in 1976. This less rigorous "clearance" to market a device based on substantial equivalency to a pre-1976 device is known as the FDCA Section 510(k) Premarket Notification process (the "510(k) clearance" process).

~~40.~~60. Section 510(k) clearance allows device manufacturers, like Defendants, to submit a relatively short "summary" to the FDA describing how their medical devices are "substantially equivalent" to a pre-1976 device (the "predicate device").

[4] U.S. Food and Drug Administration, PMA Approvals, *available at* https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals (last visited August 9, 2021).

The significant evidence needed to obtain full FDA approval of a medical device is not required when a medical device manufacturer instead applies for FDA "clearance" via the 510(k) process.

~~41.~~61. If the FDA determines that a device is "substantially equivalent" for the indicated uses to a pre-1976 device, manufacturers may obtain a fast-tracked 510(k) clearance to market the device while avoiding rigorous PMA testing for safety and effectiveness. 510(k) clearance is limited, however, to authorization to market the device ***for the indicated uses***. In submitting a 510(k) clearance application, the manufacturer must identify the device's intended use. This intended use must match the intended use of the pre-1976 device to which the manufacturer claims "substantial equivalency." *See* 21 C.F.R. § 807.81(a)(ii). If a major change or modification of the intended use is identified, the 510(k) clearance process is unavailable, and the device must go through the full PMA process instead. *Id.*

~~42.~~62. On or about September 1, 2004, National Medical Devices, Inc. (the predecessor to IMD) submitted its "Silicone Block" for Section 510(k) premarket notification of intent to market the device. National Medical Devices, Inc. submitted that the implant was substantially equivalent to an "ear, nose and throat synthetic polymer material," which is regulated as a Class II Device under 21 CFR § 874.3620, which provides:

> Ear, nose, and throat synthetic polymer material is a device material that is intended to be implanted for use as a space-occupying substance in the reconstructive surgery of the head and neck. The device is used, for example, in augmentation rhinoplasty and in tissue defect closures in the esophagus. The device is shaped and formed by the surgeon to conform to the patient's needs. This generic

type of device is made of material such as polyamide mesh or foil and porous polyethylene.

On October 25, 2004, the FDA granted 510(k) clearance to the Silicone Block that "is intended ***for use in the cosmetic correction of soft tissue deformities***, and is contoured at the surgeon's discretion to create a custom implant to aid in the reconstruction process." (Emphasis added.)

~~43.~~63. Due to certain design changes to Dr. Elist's penile implant device, on December 20, 2016, Defendants caused International Medical Devices, Inc. ("IMD")—the successor to National Medical Devices—to submit a second Section 510(k) premarket notification for a "Pre-Formed Penile Silicone Block." This application identified National Medical Device's Silicone Block, which had been cleared in 2004 based on its asserted similarity to an ear, nose, and throat reconstructive implant, as the predicate device to which IMD's Pre-Formed Penile Silicone Block was "substantially equivalent." The FDA granted 510(k) clearance on February 1, 2017, describing the "Indications for Use" as follows: "Pre-Formed Penile Silicone Block is intended for use in the cosmetic correction of soft tissue deformities, and is contoured at the surgeon's discretion to create a custom implant." Following certain additional design changes, on December 19, 2018, IMD again applied for Section 510(k) premarket notification. Again, the FDA's 510(k) clearance, dated January 23, 2019, identified the exact same "Indications for Use," *i.e.,* limited to "***use in the cosmetic correction of soft tissue deformities***."

~~44.~~64. Despite these clear limitations to the uses for which the device is FDA-cleared, Defendants regularly misrepresent Penuma as safe and effective and FDA-cleared for cosmetic enlargement of normal penises.

~~45.~~65. Penile soft tissue deformities, including Peyronie's disease, congenital micropenis, and congenital ventral curvature, are serious medical conditions that can

cause significant pain and prevent men from having sexual intercourse, in addition to shortening the penis. These deformities are rare, with Peyronie's affecting approximately 10% of men over 40, and congenital ventral curvature and congenital micropenis affecting less than 1% and 0.6% of the population, respectively. The market for a device limited to "use in the cosmetic correction of soft tissue deformities" is therefore relatively small.

46.66. A much larger market, however, exists for the cosmetic enhancement of penis size in men with normal penises. Many healthy men with normal penises desire larger penises for cosmetic reasons or to improve their sense of sexual self-confidence. This market, for which Penuma is ***neither safe and effective nor FDA-cleared***, is potentially worth millions.

47.67. Seeking to capitalize on this larger, more lucrative market, Defendants regularly falsely and misleadingly represent that Penuma is safe, effective, and FDA-cleared for "cosmetic enhancement" and advertise it as a penis enlargement device. In fact, Penuma is not safe and effective for use as a penis enlargement device and hadwas not been FDA-cleared for such use prior to May 13, 2022. Defendants regularly fail to disclose and actively conceal these facts from consumers.

68. In addition, Defendants regularly mislead consumers by representing that Penuma is "FDA cleared" to create an impression of official approval of the device, in violation of the Sherman Law, CAL. HEALTH & SAFETY CODE § 11011(a), which provides that "[a]ll regulations relating to … applications for premarket approval of new devices, adopted pursuant to [the FDCA] shall be the new drug and new device application regulations of this state." The Sherman Law incorporates 21 C.F.R. § 807.97, which prohibits representing FDA 510(k) clearance to create a misleading impression of official approval of the device. The Sherman Law also makes it unlawful "for any person to disseminate any false advertisement" as to any medical

device, stating that an "advertisement is false if it is false ***or misleading in any particular***." CAL. HEALTH & SAFETY CODE § 110390; *see Tryan v. Ulthera*, No. 17-cv-2036, 2018 WL 3955980 (E.D. Cal. Aug. 17, 2018). Defendants market Penuma on Dr. Elist's personal website, https://www.drelist.com/, as well as at http://www.penuma.com. Defendants advertise Penuma at www.penuma.com as a "Penis Enhancement Implant for Men." The same website claims that Penuma is "the first FDA-cleared penile implant for cosmetic enhancement." The website also claims that Penuma will cause "[s]ignificant, permanent cosmetic enhancements to the penis." The website is intended to and does cause a reasonable consumer to believe, falsely, that Penuma is safe and effective and FDA-cleared for cosmetic enlargement of normal penises in healthy men. and that this FDA clearance is a form of official approval of the device. Nothing on the website discloses that Penuma is FDA-cleared only for use in the cosmetic correction of soft tissue deformities. or that the FDA has not tested or approved Penuma.

69. Defendants have made these material misrepresentations and omissions consistently since at least 2017, and they continue to do so as of the date of the filing of this Complaint. For example, in a comment for a recent news article detailing the experience of numerous men who suffered painful and dangerous complications after Penuma surgery, Dr. Elist referenced the FDA clearance as showing that Penuma is safer than other penis augmentation techniques:

"The FDA has reviewed and cleared Penuma four times over nearly 20 years," Elist said. "Some of the most well-reputed prosthetic urologists use Penuma on a regular basis, including professors of urology from Rush University and Mount Sinai."Abby Ellin, *The big short*, INSIDER (March 14, 2023), *available at* https://www.insider.com/penuma-implant-penis-enlargement-enhancement-surgery-james-elist-2023-3. In an interview for another recent article in THE NEW

YORKER, which detailed the painful histories of several men who have struggled with intimate relationships and battled severe depression following their Penuma removals, Dr. Elist emphasized to the journalist that "'the best advantage of Penuma over any other procedure' was how easy it was to remove." Ava Kofman, *The Perils and Promises of Penis-Enlargement Surgery*, THE NEW YORKER (June 26, 2023), *available at* https://www.propublica.org/article/penis-enlargement-enhancement-procedures-implants.

48.70. Defendants similarly market Penuma on Dr. Elist's website as "the first FDA-cleared penile implant for cosmetic enhancement." The website's tab identifies Dr. Elist as performing "Penile Enlargement Surgery" and urges men to "Enhance and enlarge the length, girth, and size of your penis."

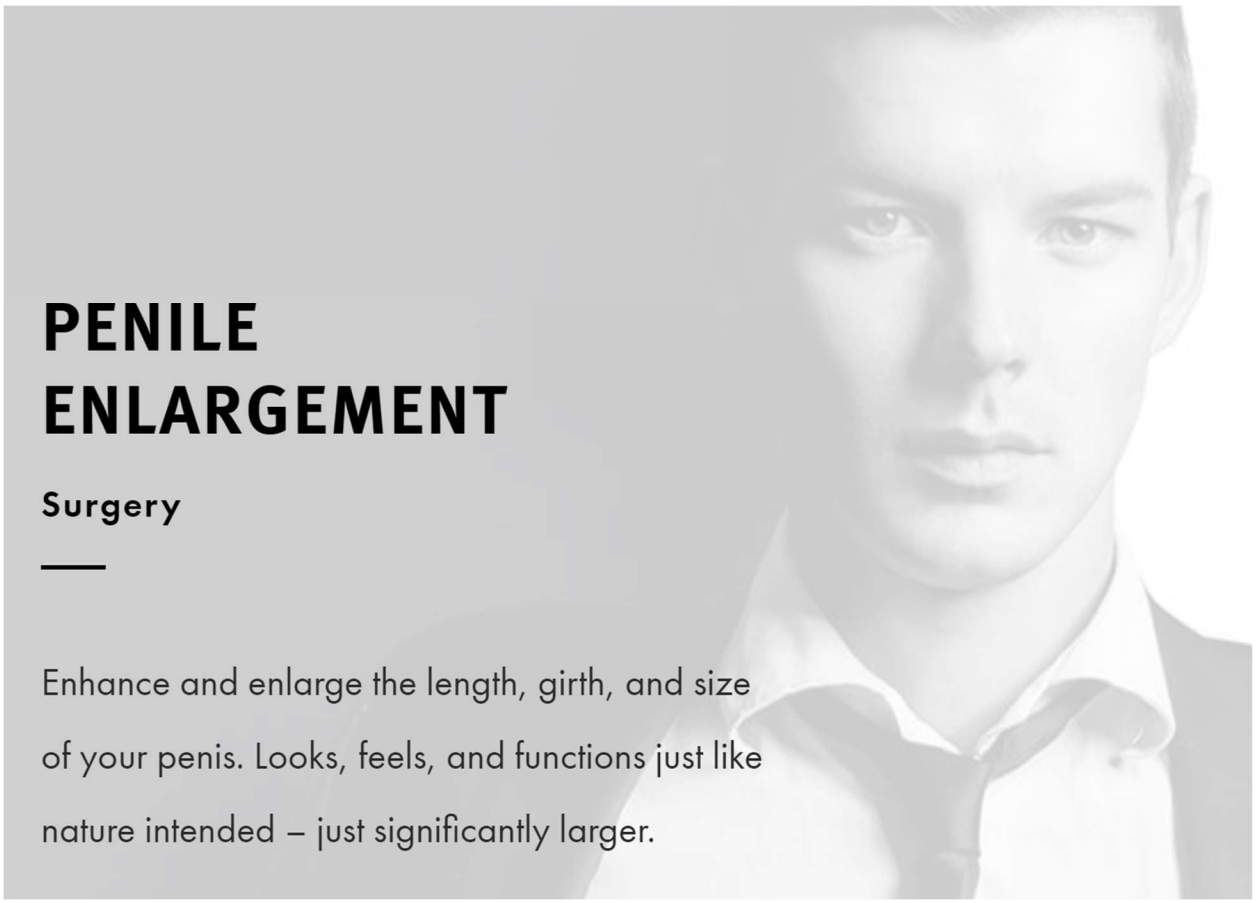


Figure 1: www.drelist.com

~~49.~~71. Gesiva's website similarly misrepresents that Penuma is "FDA-cleared for cosmetic enhancement." *See* Gesiva Medical, Penis Enlargement Surgery: Cost and Risk, *available at https://www.gesiva.com/2019/12/penis-enlargement-surgery-cost-and-risk/*.

~~50.~~72. Defendants have been making these same misrepresentations for over half a decade, at least:

2017:

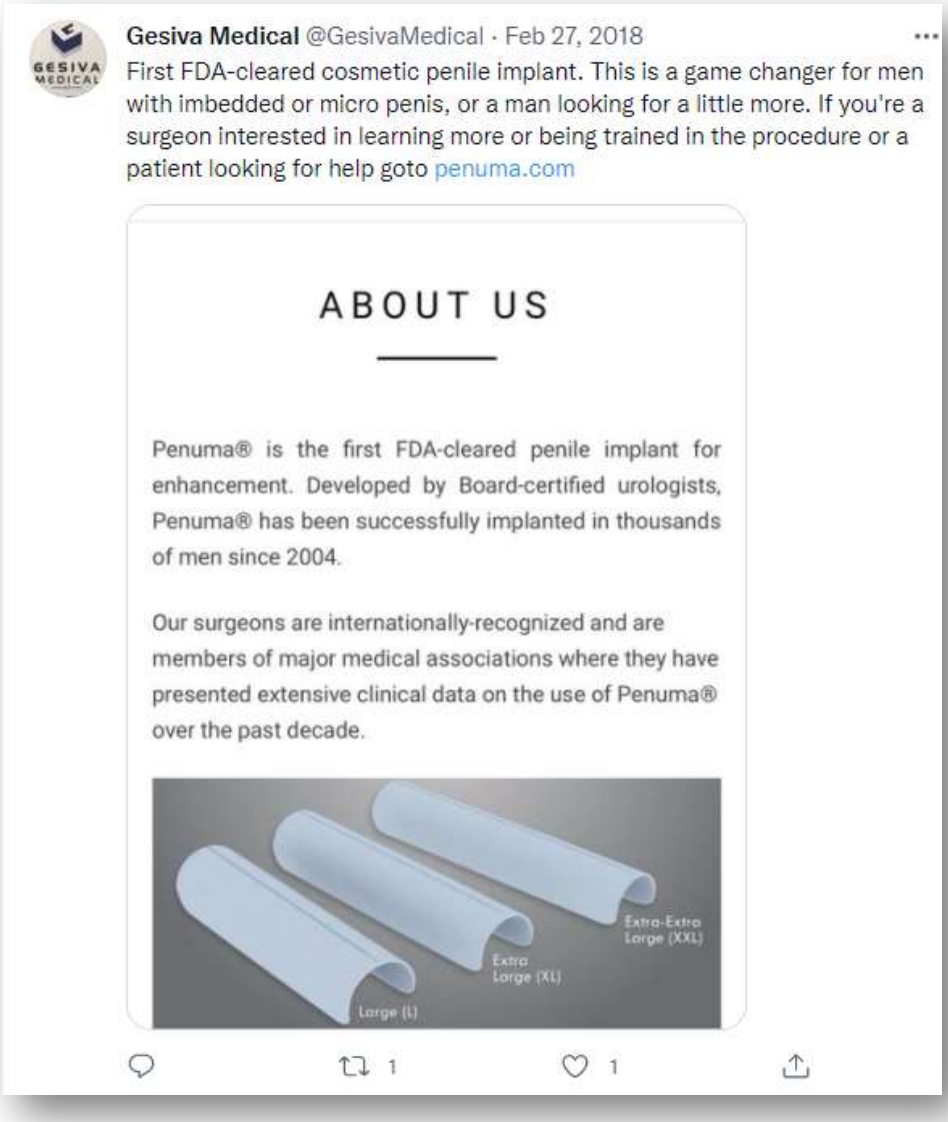
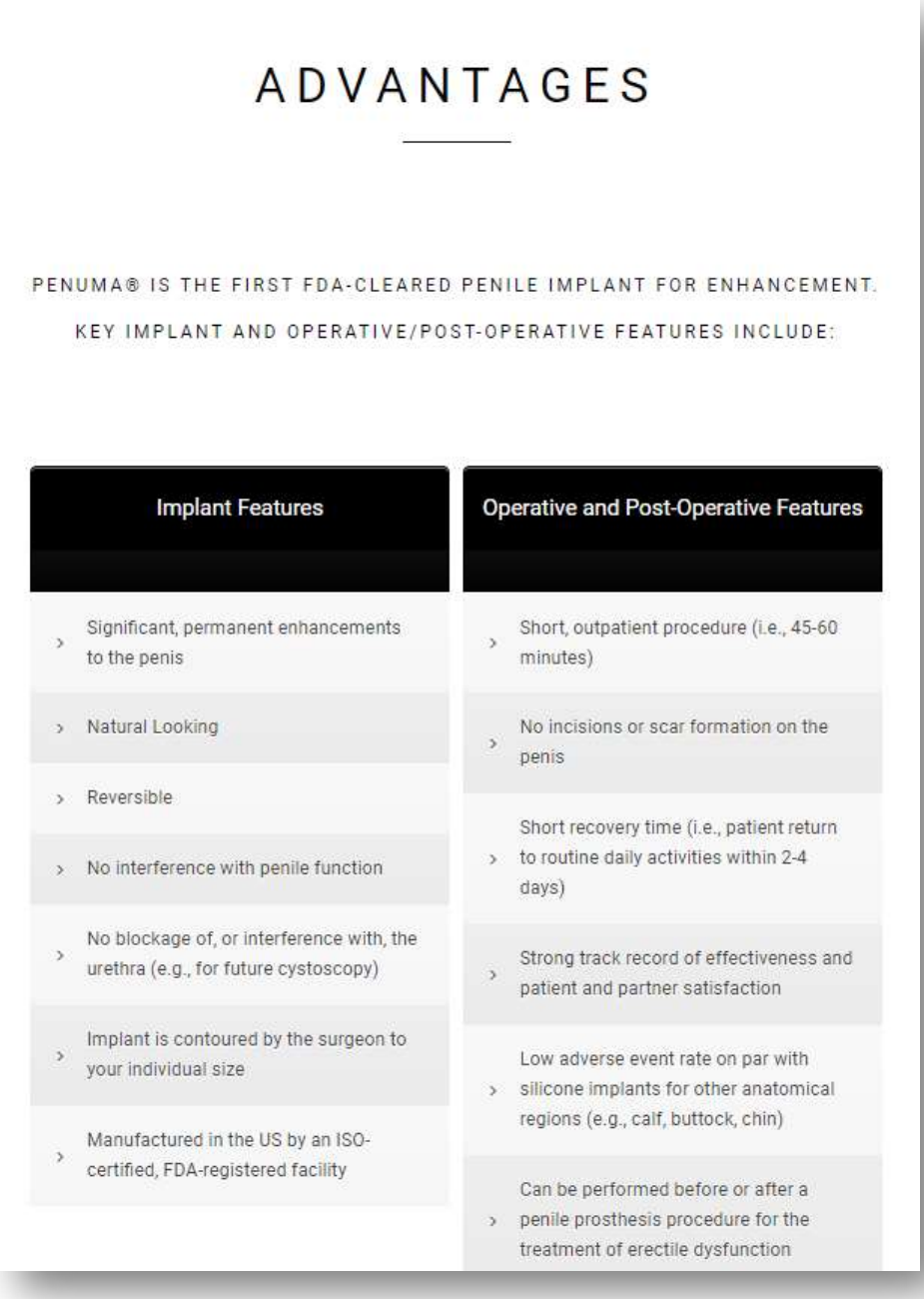


Figure 2: https://twitter.com/gesivamedical

2018



ADVANTAGES

PENUMA® IS THE FIRST FDA-CLEARED PENILE IMPLANT FOR ENHANCEMENT.

KEY IMPLANT AND OPERATIVE/POST-OPERATIVE FEATURES INCLUDE:

Implant Features	Operative and Post-Operative Features
Significant, permanent enhancements to the penis	Short, outpatient procedure (i.e., 45-60 minutes)
Natural Looking	No incisions or scar formation on the penis
Reversible	Short recovery time (i.e., patient return to routine daily activities within 2-4 days)
No interference with penile function	Strong track record of effectiveness and patient and partner satisfaction
No blockage of, or interference with, the urethra (e.g., for future cystoscopy)	Low adverse event rate on par with silicone implants for other anatomical regions (e.g., calf, buttock, chin)
Implant is contoured by the surgeon to your individual size	Can be performed before or after a penile prosthesis procedure for the treatment of erectile dysfunction
Manufactured in the US by an ISO-certified, FDA-registered facility	

Figure 3: https://web.archive.org/web/20180626111235/http://www.penuma.com/

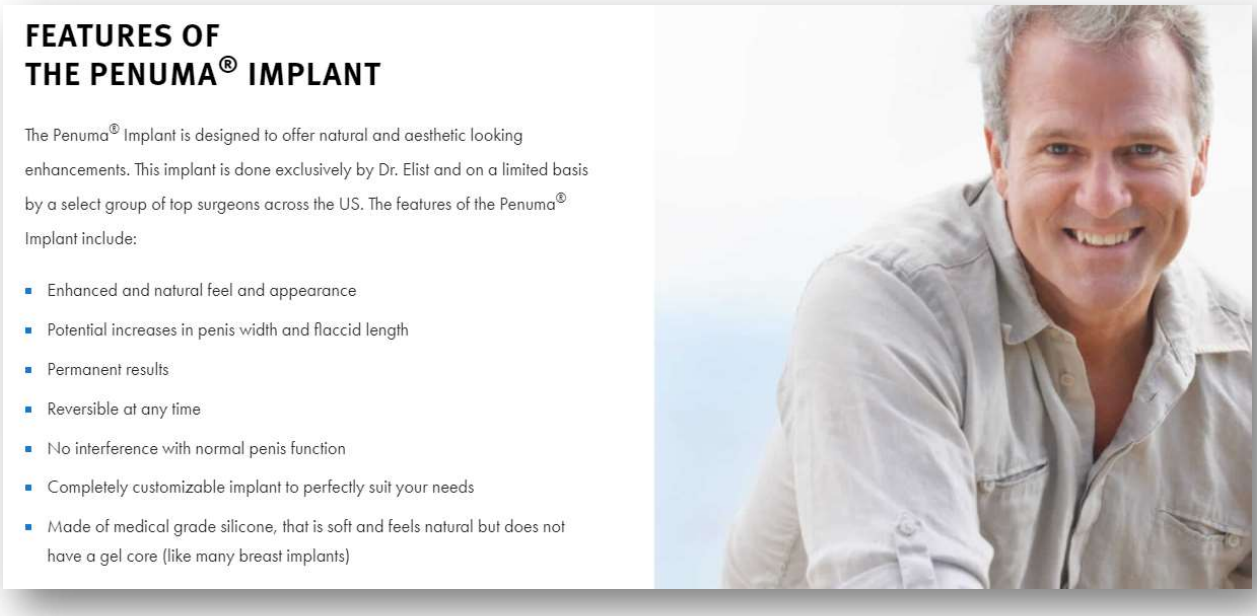


Figure 4: https://web.archive.org/web/20201001025806/https://www.drelist.com/penile-procedures/penuma-implant/

2019:

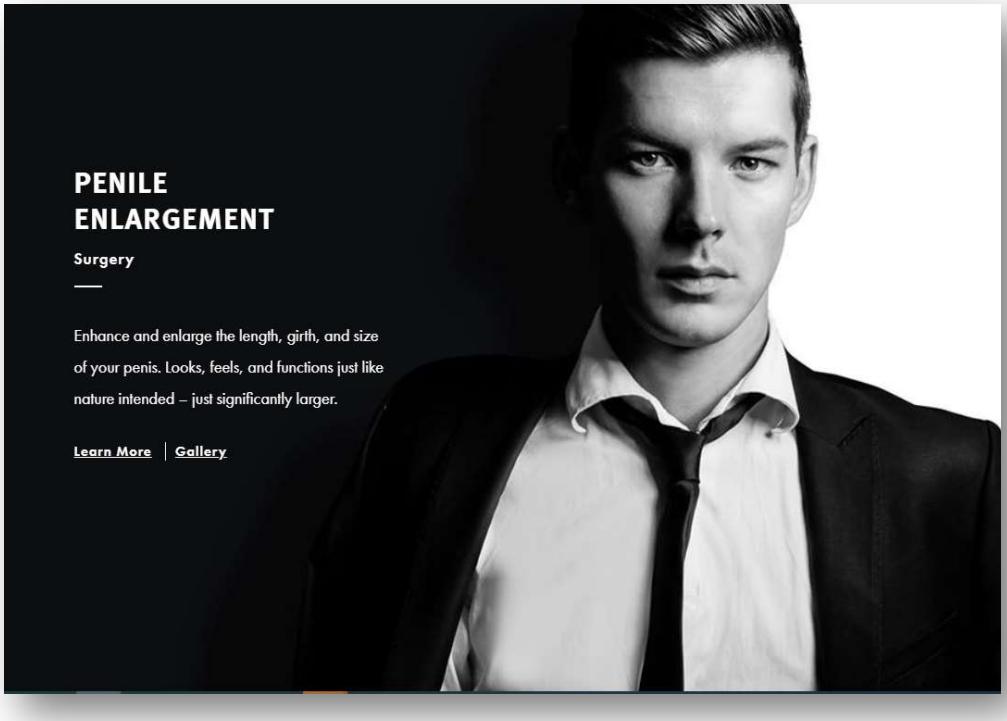
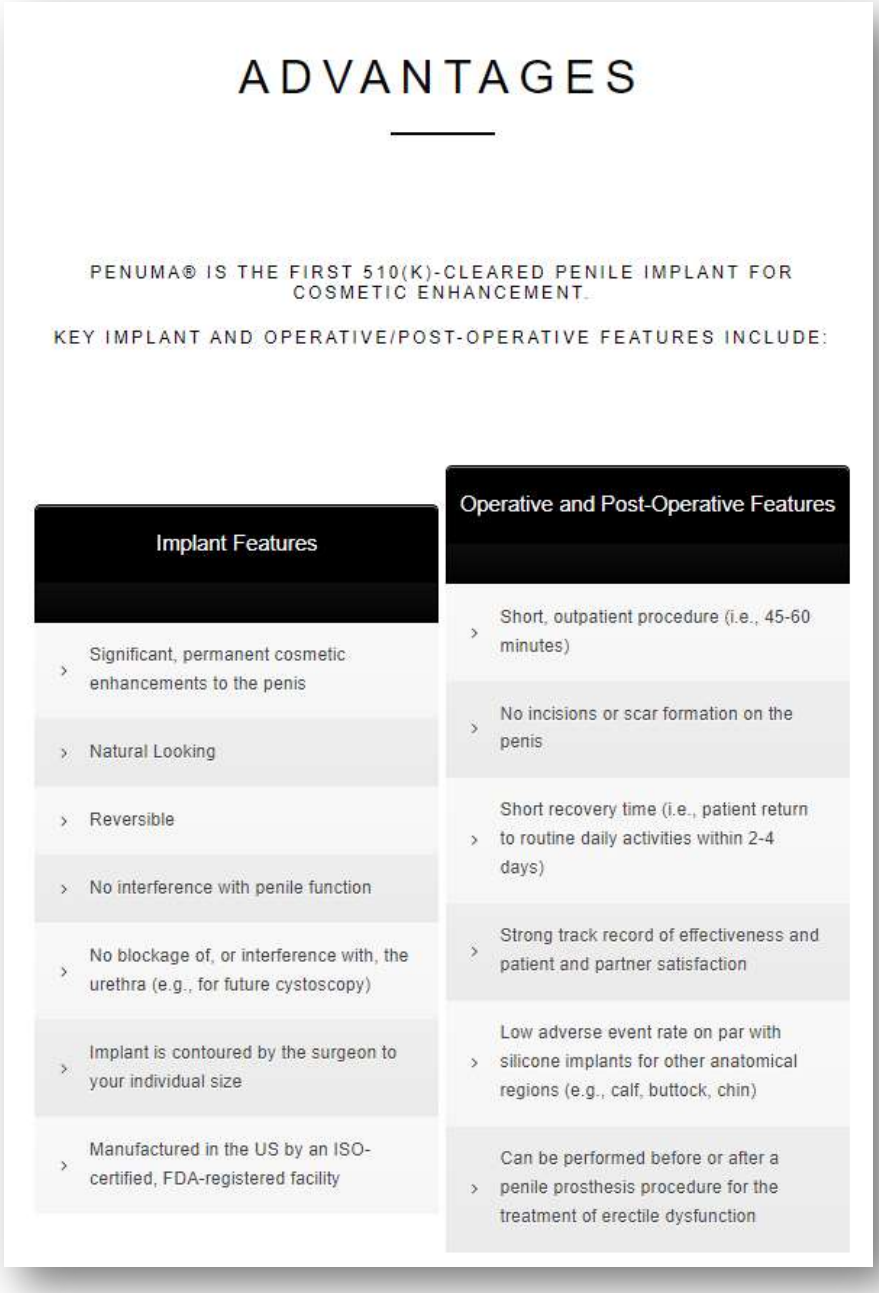


Figure 5: https://web.archive.org/web/20190714095548/https://www.drelist.com/



ADVANTAGES

PENUMA® IS THE FIRST 510(K)-CLEARED PENILE IMPLANT FOR COSMETIC ENHANCEMENT.

KEY IMPLANT AND OPERATIVE/POST-OPERATIVE FEATURES INCLUDE:

Implant Features	Operative and Post-Operative Features
Significant, permanent cosmetic enhancements to the penis	Short, outpatient procedure (i.e., 45-60 minutes)
Natural Looking	No incisions or scar formation on the penis
Reversible	Short recovery time (i.e., patient return to routine daily activities within 2-4 days)
No interference with penile function	Strong track record of effectiveness and patient and partner satisfaction
No blockage of, or interference with, the urethra (e.g., for future cystoscopy)	Low adverse event rate on par with silicone implants for other anatomical regions (e.g., calf, buttock, chin)
Implant is contoured by the surgeon to your individual size	Can be performed before or after a penile prosthesis procedure for the treatment of erectile dysfunction
Manufactured in the US by an ISO-certified, FDA-registered facility	

Figure 6: https://web.archive.org/web/20190609121832/https://www.penuma.com/

2020:

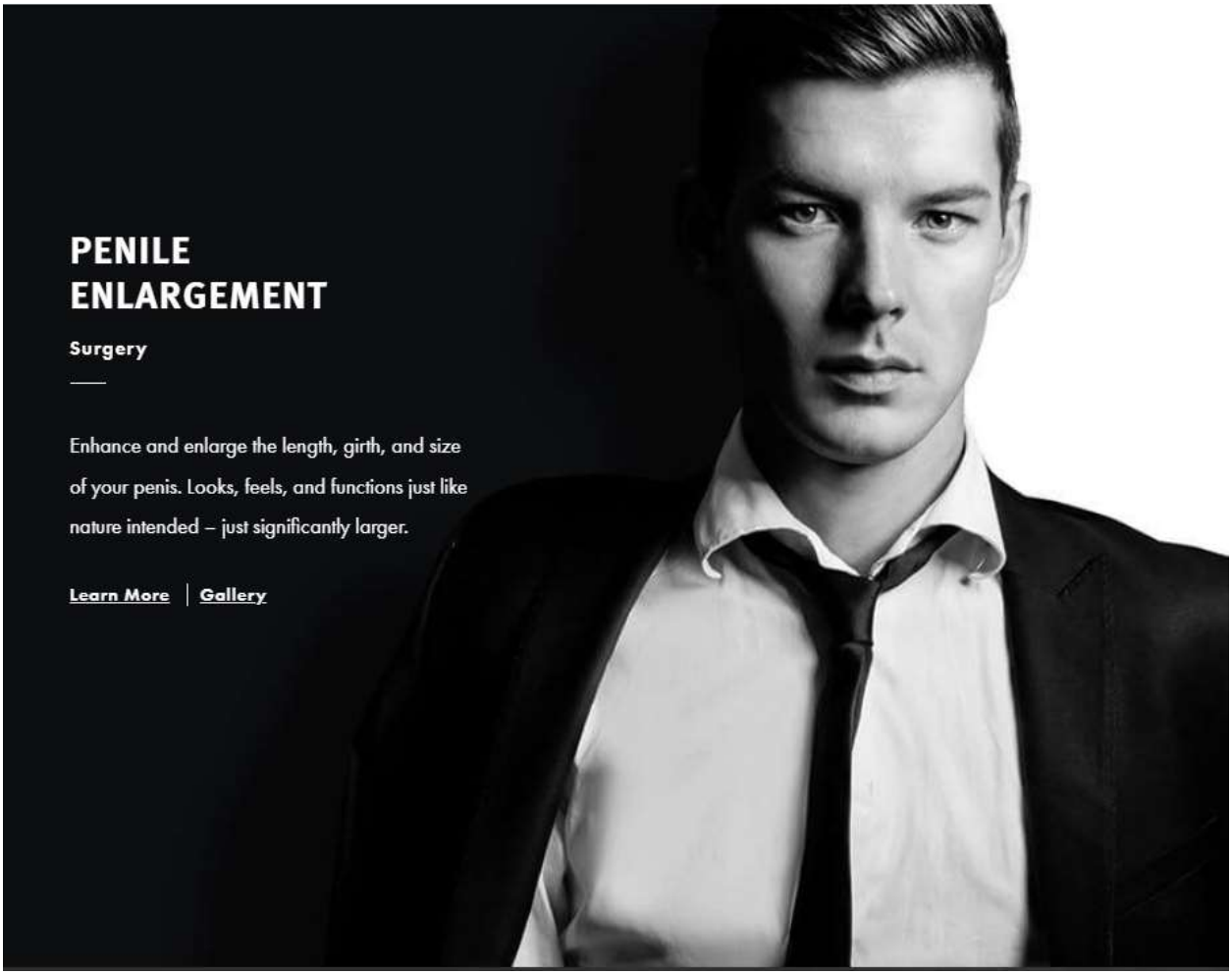
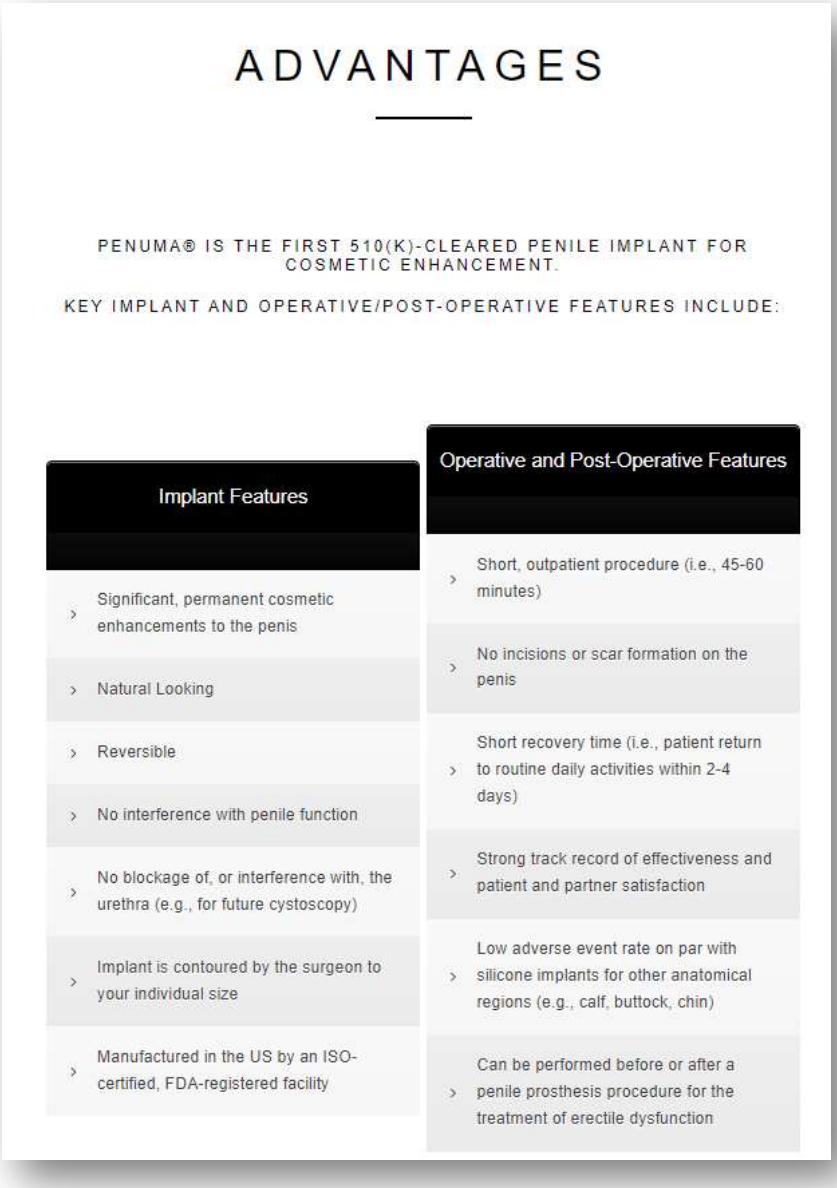


Figure 7: https://web.archive.org/web/20200701020552/https://www.drelist.com/



ADVANTAGES

PENUMA® IS THE FIRST 510(K)-CLEARED PENILE IMPLANT FOR COSMETIC ENHANCEMENT.

KEY IMPLANT AND OPERATIVE/POST-OPERATIVE FEATURES INCLUDE:

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No blockage of, or interference with, the urethra (e.g., for future cystoscopy)	Low adverse event rate on par with silicone implants for other anatomical regions (e.g., calf, buttock, chin)
Implant is contoured by the surgeon to your individual size	Can be performed before or after a penile prosthesis procedure for the treatment of erectile dysfunction
Manufactured in the US by an ISO-certified, FDA-registered facility	

Figure 8: https://web.archive.org/web/20190609121832/https://www.penuma.com/

2021:

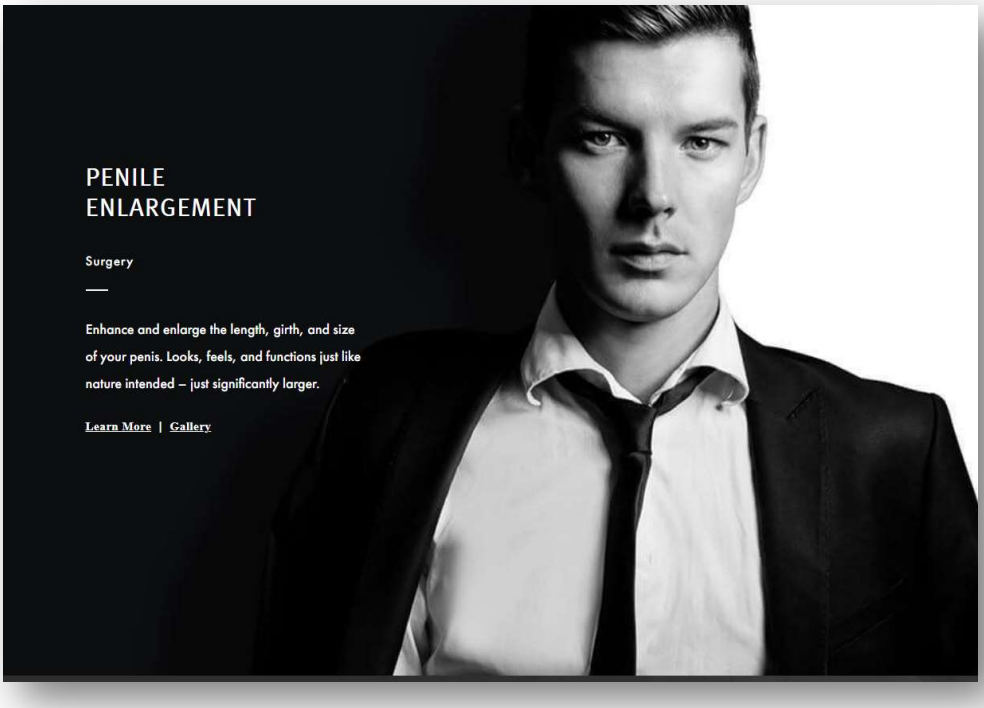

Figure 9: https://www.drelist.com/

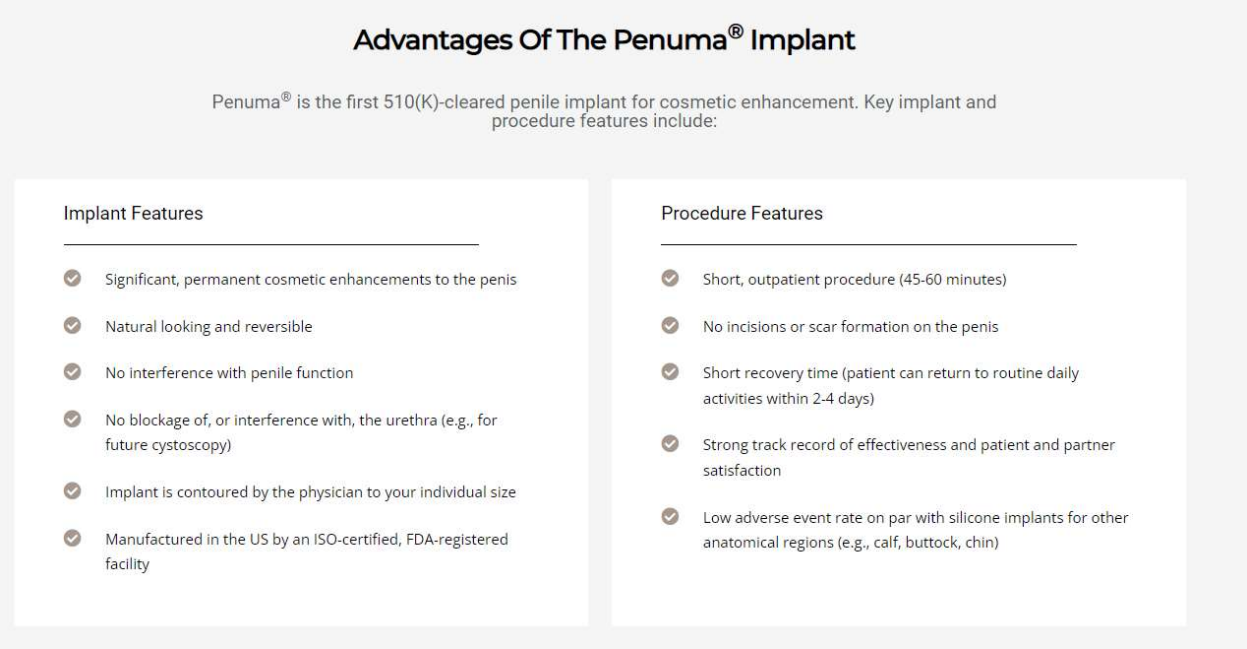

Figure 10: https://penuma.com/

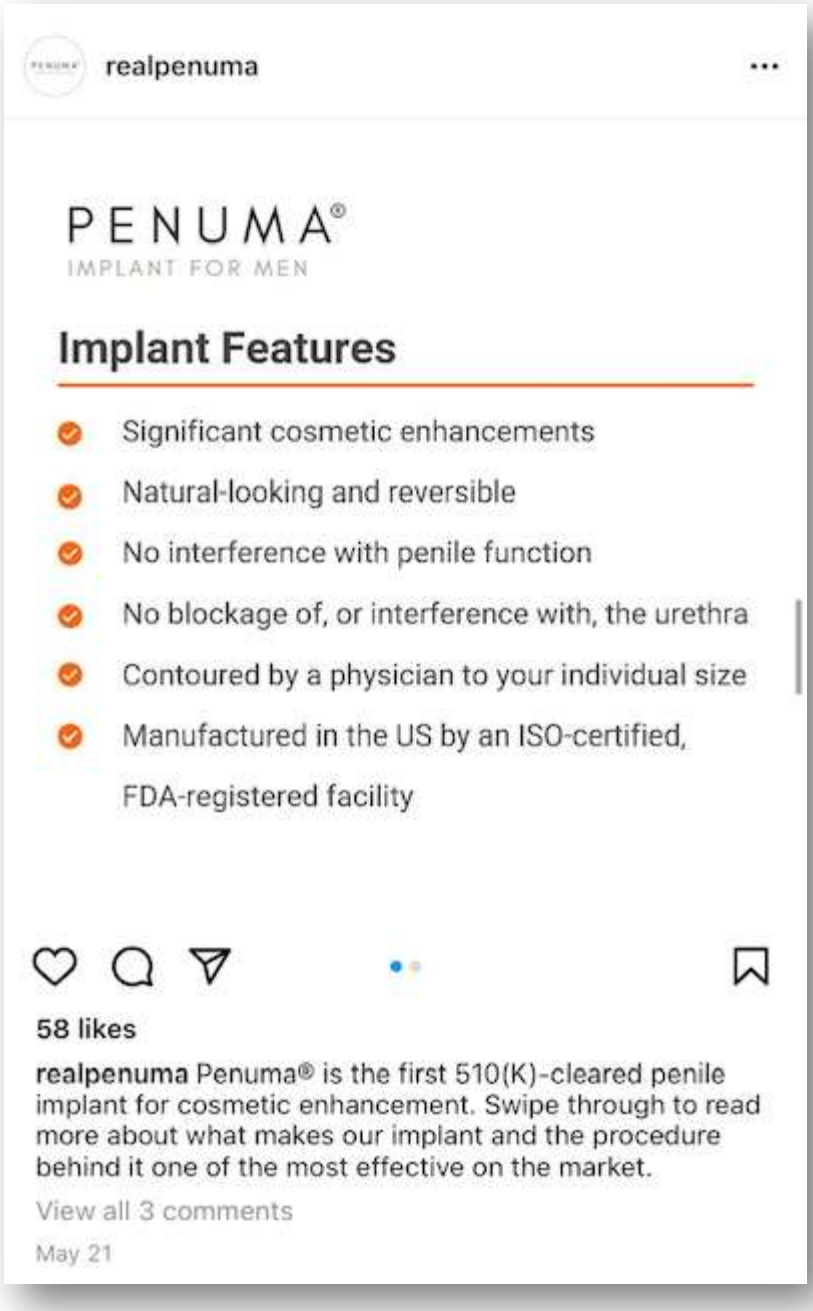

Figure 11: https://www.instagram.com/realpenuma/?hl=en

~~51.~~73. The websites are intended to and do cause a reasonable consumer to believe, falsely, that Penuma is safe and effective ~~and FDA-cleared for cosmetic enlargement of normal penises in healthy men.~~. Nothing on the websites discloses that Penuma ~~is~~was FDA-cleared only for use in the cosmetic correction of soft tissue deformities until May 13, 2022, that its FDA clearance does not in any way denote official approval of the device, that it is not effective to enhance the appearance of normal penises, or that it frequently causes complications that require the implant to be removed, causing permanent damage to the penis.

~~52.~~74. In fact, Defendants have no data to support any claim that Penuma will cause an increase in penile length. To the contrary, implantation of the Penuma device frequently causes scarring, resulting in the penis becoming shorter. When the Penuma is placed, a sheath of scar tissue—termed a "pseudocapsule"—forms around the entire foreign body. This is the body's reaction to healing. Because scar tissue does not stretch, when the penis fills with blood during an erection, the ventral surface of the penis stretches and becomes longer, but the dorsal surface is restricted by the pseudocapsule. This results in a dorsal curvature and apparent shortening of the erection. Neither IMD nor Dr. Elist acknowledges these complications. Instead, their website simply shuffles consumers to their self-published study—a study which Dr. Elist himself admits had skewed results because over a hundred patients (approximately 24% of the potential pool) refused to participate.

~~53.~~75. Dr. Elist and IMD similarly tout that the post-Penuma penis is "natural looking," indicating that it is effective for cosmetic enhancement in men with normal, healthy penises; however, many patients experience a penguin or batwing

shape post-surgery, causing the body of the penis to be wider than the head of the penis:

54.76. Defendants also claim that the Penuma procedure is "reversible." The prevailing medical literature disagrees, concluding that in "all patients in our series, corrective surgery resulted in both cosmetic and functional improvement. However, **none** resulted in a completely normal penis, as was the appearance prior to initial enhancement surgery":[5]

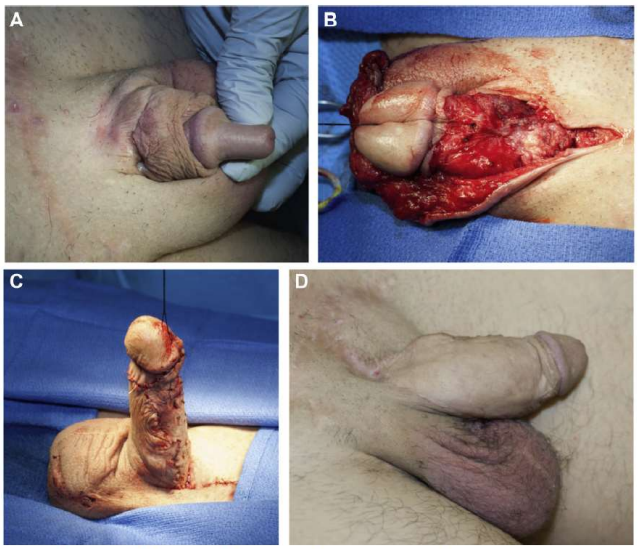

Figure 4. Severe penile deformity and ulceration and loss of penile length after penis enlargement surgery with a subcutaneous silicone penile implant (A). Following removal and debridement (B), inadequate dorsal skin coverage required skin grafting (C and D). Figure 4 is available in color online at www.jsm.jsexmed.org.

[5] Furr, *Complications of Genital Enlargement Surgery*, 15 SEX. MED. REV. 1811–17, 1816 (2018) (emphasis added).

~~55.~~77. Defendants also claim that the Penuma implant causes no interference with normal penis function. Yet many patients experience sexual dysfunction, including loss of sensation, as a consequence of ~~the~~ receiving the Penuma implant.

~~56.~~78. Defendants knew when they made these representations that Penuma was not safe and effective or FDA-cleared for cosmetic enhancement of normal penises prior to May 13, 2022, that FDA clearance does not in any way denote official approval of the device, and that the procedure frequently caused side effects requiring removal of the device. Defendants also knew that the Penuma procedure could not be reversed without permanent damage to the penis, but they nevertheless failed to disclose and actively concealed this information from ~~Plaintiff~~Plaintiffs and the Class members.

~~57.~~79. Dr. Elist and other doctors performing Penuma implant surgery regularly refer patients to the Penuma website and to Dr. Elist's website for information regarding the Penuma device. In making the representations and omissions described above, Defendants intend for consumers to rely on their representations that Penuma is a safe and effective, FDA-cleared device for cosmetic penile enlargement that is permanent and reversible, and thousands of reasonable consumers did in fact so rely.

~~58.~~80. ~~Plaintiff~~Plaintiffs and the Class members purchased the Penuma device and implantation procedure in reasonable reliance on Defendants' misrepresentations that Penuma was safe and effective and FDA-cleared for cosmetic enhancement and that it was permanent and could be reversed without negative consequences. ~~Plaintiff~~Plaintiffs and Class members also relied on Defendants' misrepresentations that the Penuma implant would result in a natural looking penis and that the implant would cause no interference with normal penis function. If ~~Plaintiff~~Plaintiffs and the Class members had known that Penuma was

not safe and effective ~~or~~, that it had not been FDA-cleared for the cosmetic enhancement of normal penises prior to May 13, 2022, that FDA clearance did not in any way denote official approval of the device, that Defendants in fact had no data to support any claims of increase in penis length as a result of the procedure, that the implant often interfered with normal penis function, and that the procedure frequently led to complications requiring removal of the device, resulting in permanent damage to the penis, they would not have purchased the device and would not have had the implantation procedure performed.

C. ~~Plaintiff~~Plaintiffs and the Class members paid thousands of dollars for a product and service that had no value.

~~59.~~81. The total cost for purchase of the Penuma device and the implantation surgery ranges from $14,500–$20,000. Of this payment, approximately $6,000 is paid to IMD for purchase of the Penuma device. Because the procedure is cosmetic, it is not covered by medical insurance. All Defendants profit, either directly or indirectly, from the sales of the Penuma device to patients.

~~60.~~82. Dr. Elist has performed thousands of Penuma implantation procedures at his clinic in Beverly Hills. He has also, with Gesiva's help, marketed and licensed his Penuma implantation procedures to 12 doctors nationwide, who all perform the surgery in substantially the same manner, using the product and procedure developed by Dr. Elist in his Beverly Hills clinic, resulting in substantial profits to Defendants.

~~61.~~83. The actual value of the procedure, however, is non-existent. Instead of the cosmetic enlargement of the penis consumers were misled to expect, Penuma does not increase the length of patients' flaccid penises, but causes disfigurement and scarring that often leads to a shortening of the erect penis in the majority of cases. The scarring also often interferes with normal penis function by reducing sensation in the penis, leading to sexual dysfunction.

~~62.~~84. Not only does the procedure not produce the cosmetic enhancement consumers are misled to expect, but it also frequently causes painful infections that lead to yet more scarring. A substantial number of men have had to have the Penuma device removed because of such infection and scarring, leading to a loss of sensation in and/or permanent shortening of the penis.

~~63.~~85. When infection, disfigurement, or other complications require the Penuma to be removed, patients suffer a significant shortening of their non-erect penises. Because the pseudocapsule of scar tissue, which is attached to the penile shaft, contracts over time after removal of the Penuma device, patients' flaccid penises appear shorter—often one to two inches shorter. The same shortening appears in the erect penises of patients who have had the Penuma removed.

~~64.~~86. These complications have been well-reported in medical literature. A 2021 article specially identified "penile shortening and erectile dysfunction (ED)" as "reported complications in literature" following Penuma removal.[6] A 2018 article also from the Journal of Sexual Medicine similarly identified "penile shortening due to fibrosis."[7]

~~65.~~87. Given these risks, reputable urologists recognize that penile implant procedures, including the Penuma procedure, are not safe and effective for cosmetic enhancement in men with normal penises. For example, the Mayo Clinic notes that penis-enlargement surgery is "experimental" and should be reserved for "men whose penises don't function normally because of a birth defect or injury":

> The need for penis-enlargement surgery is rare. Surgery is typically reserved for men whose penises don't function

[6] Kapadia et al., *Evaluation and Treatment of Complications of Penuma Penile Implant*, 18 JOURNAL OF SEXUAL MEDICINE 80 (2021).

[7] Furr et al., *Complications of Genital Enlargement Surgery*, 15 J. SEX. MED. 1811 (2018).

> normally because of a birth defect or injury. Although some surgeons offer cosmetic penis enlargement using various techniques, it's controversial and considered by many to be unnecessary and in some cases permanently harmful. These surgeries should be considered experimental.

Mayo Clinic, *Penis-enlargement products: Do they work?*, *available at* https://www.mayoclinic.org/healthy-lifestyle/sexual-health/in-depth/penis/art-20045363 (last visited Sept. 23, 2021); *see also Marra*, *Systematic Review of Surgical and Nonsurgical Interventions in Normal Men Complaining of Penis Size*, 8 SEX. MED. REV. 158, 177 (2020) ("We believe that surgery should be a last resort, undertaken as an experimental treatment only in a clinical trial setting after expert psychosexual assessment.")

88. Dr. Elist's practices regarding Penuma have led to numerous complaints to the California Medical Board, including for gross negligence, repeated negligent acts, and incompetence. On March 8, 2023, the California Medical Board filed its Fifth Amended Accusation *In the Matter of the Fifth Amended Accusation Against James Jamshid Elist, M.D.*, No. 800-2018-048274 (March 8, 2023), *available at* https://www2.mbc.ca.gov/BreezePDL/document.aspx?path=%5CDIDOCS%5C20230308%5CDMRAAAJD3%5C&did=AAAJD230309001531190.DID. The Accusation alleges that Dr. Elist was grossly negligent in offering surgical penile augmentation to patients with a diagnosis of penile dysmorphia rather than, as indicated by the standard of care in the medical community, referring such patients to a mental health professional. (*Id.* ¶ 8.) The Fifth Amended Accusation further alleges that Dr. Elist "committed an extreme departure from the standard of care …

by failing to disclose that the implant to be used has not been fully FDA-Approved." (*Id.* ¶ 142.)

~~66.~~89. As a result of their reliance on Defendants' representations and omissions, consumers have suffered an ascertainable loss of money, namely, the cost of purchasing the Penuma device and procedure. Further, as a result of their deceptive marketing and unfair competition, Defendants realized sizable profits.

~~67.~~90. As the intended, direct, and proximate result of Defendants' false, misleading, and deceptive representations and omissions, Defendants have been unjustly enriched through sales of Penuma devices and procedures at the expense of ~~Plaintiff~~Plaintiffs and the Class members.

~~68.~~91. ~~Plaintiff~~Plaintiffs and Class Members have also suffered irreparable injury from these false representations. Their bodily integrity has been violated, creating a substantial risk of permanent injury. ~~Plaintiff continues~~Plaintiffs continue to desire a safe, effective penile implant. If the Penuma device and procedure were redesigned to be safe and effective for cosmetic penile enlargement~~, FDA-cleared for this use,~~ and truthfully marketed, ~~Plaintiff~~Plaintiffs would purchase a Penuma device and procedure in the future. There is a threat that ~~Plaintiff~~Plaintiffs and the Class members will purchase the Penuma device or procedure in the future, despite the fact that it was once marred by false advertising, because they may reasonably, but incorrectly, assume the product was improved. On information and belief, multiple men have paid Dr. Elist for repeated procedures based on misrepresentations that their initial poor results were unusual and that subsequent procedures would improve the results. In the alternative, because of Defendants' false, misleading, and deceptive representations and omissions, there is a threat that ~~Plaintiff~~Plaintiffs and the Class members will be unable to rely on Penuma's advertising or labeling in the future, and so will not purchase a Penuma device or

procedure although they would like to. Due to the continuing imminent threat of such injuries, ~~Plaintiff~~Plaintiffs and Class members have no adequate remedy at law, and ~~Plaintiff~~Plaintiffs and Class members are therefore entitled to injunctive relief.

~~69.~~92. ~~Plaintiff~~Plaintiffs and the Class members suffered injuries in fact caused by the false, fraudulent, unfair, deceptive, and misleading practice alleged herein and accordingly seek restitution and injunctive relief.

D. Class Definition

~~Plaintiff brings~~Plaintiffs bring this lawsuit as a class action on behalf of himself and on behalf of the following Class and Pre-May 13, 2022 Subclass:

> **Class:**
>
> All individuals in the United States, including its territories and the District of Columbia, who purchased a Penuma device and implantation procedure and whose procedures were performed by Dr. James Elist at the Beverly Hills South Pacific Surgery Center from ~~four years prior to the filing of this complaint~~May 19, 2018 through the date of certification.
>
> **Pre-May 13, 2022 Subclass:**
>
> All Class members whose procedures were performed from May 19, 2018 to May 12, 2022.

Excluded from the Class are (1) any employees, officers, directors, or immediate family members of Defendants; (2) any attorneys appearing in this case; (3) any judges assigned to hear this case, as well as their immediate family and staff; (4) any judges who may hear an appeal in this case, as well as their immediate family and staff; (5) any individuals whose Penuma implantation procedures were covered by

medical insurance; ~~(6) any individuals who have been diagnosed with a soft tissue deformity of the penis; and (7~~and (6) any individuals who have filed an individual action for personal injuries caused by the Penuma device and/or procedure. Excluded from the Pre-May 13, 2022 Subclass are any individuals who have been diagnosed with a soft tissue deformity of the penis.

~~70.~~93. **Ascertainability**. **FED. R. CIV. P. 23(a)**. The Class is ascertainable in that they comprise individuals who can be identified by reference to purely objective criteria, including information in Defendants' business records. Notice may be mailed to members of the Class using the information in Defendants' files, as updated through the National Change of Address Registry and other commercially available means.

~~71.~~94. **Numerosity**. **FED. R. CIV. P. 23(a)(1)**. The Class is so numerous that joinder of all members is impracticable. Although the precise number of Class members is not currently known, the scope of Penuma's sales and Dr. Elist's practice shows that the Class likely consists of at least hundreds of persons and, therefore, it would be impracticable to bring all these persons before the Court as individual plaintiffs.

~~72.~~95. **Typicality**. **FED. R. CIV. P. 23(a)(3)**. Plaintiff's claims are typical of each member of the Class he seeks to represent. These claims all arise from the same operative facts and are based on the same legal theories.

~~73.~~96. **Adequacy of Representation**. **FED. R. CIV. P. 23(a)(4)**. ~~Plaintiff~~Plaintiffs will fairly and adequately protect the interests of the Class members. ~~Plaintiff is~~Plaintiffs are committed to vigorously litigating this matter, and ~~his~~their interests are aligned with those of the Class. ~~Plaintiff has~~Plaintiffs have retained counsel experienced in handling consumer class action litigation.

~~74.~~97. **Commonality and Predominance**. **FED. R. CIV. P. 23(a)(2) & (b)(3)**. Common issues of law and fact exist regarding ~~Plaintiff's~~Plaintiffs' and the Class members' claims and predominate over any individual issues. These common issues include:

(a) whether Defendants misrepresented that Penuma was FDA-cleared for cosmetic enhancement of normal penises prior to May 13, 2022;

(b) whether Defendants misleadingly represented that Penuma was FDA-cleared to create an impression of official approval of the device;

~~(b)~~(c) whether the Penuma device and procedure are safe and effective for cosmetic penis enlargement;

~~(c)~~(d) whether Defendants falsely and misleadingly marketed Penuma as a cosmetic penis enlargement device;

~~(d)~~(e) whether Defendants misrepresented that Penuma was permanent;

~~(e)~~(f) whether Defendants misrepresented that the Penuma procedure was reversible;

~~(f)~~(g) whether Defendants misrepresented that the Penuma device results in a ~~normal~~natural looking penis;

~~(g)~~(h) whether Defendants misrepresented that the Penuma device causes no interference with penile function;

~~(h)~~(i) whether Defendants' marketing of the Penuma device and procedure is an unfair business practice;

~~(i)~~(j) whether Defendants violated California's False Advertising Law;

~~(j)~~(k) whether Defendants violated California's Consumer Legal Remedies Act;

~~(k)~~(l) whether Defendants violated California's Unfair Competition Law;

~~(l)~~(m) whether injunctive relief is appropriate; and

~~(m)~~(n) the appropriate measure of restitution.

~~75.~~98. **Superiority**. **FED. R. CIV. P. 23(b)(3)**. A class action is a superior method for the fair and efficient adjudication of this controversy. The interests of Class members in individually controlling the prosecution of separate claims against Defendant is small, as the maximum damages recoverable by any one Class member is limited. Management of the Class's claims in a single proceeding will avoid inconsistent judgments and result in a more efficient use of judicial resources than resolving these same issues in many individual cases.

~~76.~~99. **Injunctive Relief Appropriate to the Class**. **FED. R. CIV. P. 23(b)(2)**. This action should also be maintained as a class action because Defendants have acted or refused to act on grounds that apply generally to the Class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the Class as a whole.

VII. CLAIMS

COUNT ONE – Violation of California's False Advertising Law, CAL. BUS. & PROF. CODE § 17500 ("FAL")

~~77.~~100. ~~Plaintiff incorporates~~Plaintiffs incorporate by reference all of the foregoing allegations as if they were fully set forth here.

~~78.~~101. ~~Plaintiff brings~~Plaintiffs bring this claim individually and on behalf of the Class members against all Defendants.

~~79.~~102. The FAL provides that "[i]t is unlawful for any person, firm, corporation or association, or any employee thereof with intent directly or indirectly to dispose of real or personal property or to perform services" to disseminate any statement "which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading." CAL. BUS. & PROF. CODE § 17500.

~~80.~~103. It is also unlawful under the FAL to disseminate statements concerning property or services that are "untrue or misleading, and which [are] known, or which by the exercise of reasonable care should be known, to be untrue or misleading." *Id.*

~~81.~~104. As alleged herein, Defendants' advertisements relating to the Penuma device and implantation procedure misled reasonable consumers as to the uses for which Penuma had been cleared for use by the FDA, as to whether the FDA had officially approved of the device in any way, as to its safety and effectiveness for use as a penis enlargement device, and as to whether the procedure was permanent, natural looking, and reversible.

~~82.~~105. The FAL applies to Defendants' advertisements because the marketing decisions that that led to the false and misleading advertising were made in California.

~~83.~~106. Defendants' business practices alleged herein constitute deceptive, untrue, and misleading advertising pursuant to the FAL because Defendants knew or reasonably should have known that their advertisements were untrue and misleading, and Defendants omitted material information from their advertising.

~~84.~~107. Defendants profited from their sale of the falsely and deceptively advertised device and procedure.

~~85.~~108. As a result, Plaintiff, the Class, and the general public are entitled to injunctive and equitable relief, restitution, and an order for the disgorgement of the funds by which Defendants were unjustly enriched.

~~86.~~109. Pursuant to CAL. BUS. & PROF. CODE § 17535, Plaintiff, on behalf of himself and the Class, seeks an order enjoining Defendants from continuing to engage in deceptive business practices and false advertising.

COUNT TWO – Violation of California's Consumers Legal Remedies Act, CAL. CIV. CODE § 1750 *et seq.* ("CLRA")

~~87.~~110. ~~Plaintiff incorporates~~Plaintiffs incorporate by reference all of the foregoing allegations as if they were fully set forth here.

~~88.~~111. ~~Plaintiff brings~~Plaintiffs bring this claim individually and on behalf of the Class members against all Defendants.

~~89.~~112. The California Consumer Legal Remedies Act ("CLRA") prohibits deceptive practices in connection with the conduct of a business that provides goods, property, or services primarily for personal, family, or household purposes.

~~90.~~113. The CLRA applies to Defendants' conduct because the marketing decisions that that led to the false and misleading advertising were made in California and the surgical procedures at issue were performed in California.

~~91.~~114. Defendants are "person(s)" as defined by CAL. CIV. CODE § 1761(c).

~~92.~~115. ~~Plaintiff~~Plaintiffs and the Class members are "consumers" within the meaning of CAL. CIV. CODE § 1761(d) because they purchased the Penuma device and procedure for personal purposes.

~~93.~~116. Defendants' false and misleading advertising was designed to and did induce the purchase of the Penuma device and implantation procedure for

personal, family, or household purposes by ~~Plaintiff~~Plaintiffs and the Class members, in violation of the following sections of the CLRA:

(a) § 1770(a)(5): representing that goods have characteristics, uses, or benefits which they do not have;

(b) § 1770(a)(7): representing that goods are of a particular standard, quality, or grade if they are of another; and

(c) § 1770(a)(9): advertising goods with intent not to sell them as advertised.

~~94.~~117. Defendants knew the Penuma device and procedure did not ~~posses~~possess the characteristics and benefits as represented and were not of the particular standard, quality, or grade as represented.

~~95.~~118. Defendants had a duty to ~~Plaintiff~~Plaintiffs and the Class members to disclose the scope of intended uses for which the Penuma device and procedure were safe and effective and FDA-cleared because:

(a) Defendants were in a superior position to know the scope of intended uses for which the Penuma device and procedure were safe and effective and FDA-cleared;

(b) ~~Plaintiff~~Plaintiffs and the Class members could not reasonably have been expected to know the scope of intended uses for which the Penuma device and procedure were safe and effective and FDA-cleared; and

(c) Defendants knew that ~~Plaintiff~~Plaintiffs and the Class members could not reasonably have been expected to know the scope of intended uses for which the Penuma device and procedure were safe and effective and FDA-cleared.

119. Defendants had a duty to the Class members to disclose that Penuma had not been tested or approved by the FDA because:

(a) Defendants were in a superior position to know that Section 510(k) premarket clearance does not in any way denote official approval of the device;

(b) Plaintiffs and the Class members could not reasonably have been expected to know that Section 510(k) premarket clearance does not in any way denote official approval of the device; and

(c) Defendants knew that Plaintiffs and the Class members could not reasonably have been expected to know that Section 510(k) premarket clearance does not in any way denote official approval of the device.

~~96.~~120. In failing to disclose and misrepresenting the scope of intended uses for which the Penuma device and procedure were safe and effective and FDA-cleared and in failing to disclose that Penuma was not FDA approved, Defendants knowingly and intentionally concealed material facts and breached their duty not to do so.

~~97.~~121. The facts Defendants concealed from and/or misrepresented to ~~Plaintiff~~Plaintiffs and the Class members are material in that a reasonable consumer would have considered them to be important in deciding whether to purchase the Penuma device and procedure. If ~~Plaintiff~~Plaintiffs and the Class members had known that Penuma was not safe and effective or FDA-cleared for cosmetic enhancement of normal penises, ~~or that it~~that FDA clearance did not in any way denote official approval of the device, or that Penuma was not permanent and

frequently led to complications requiring removal, causing permanent damage to the penis, they would not have purchased the device and procedure.

~~98.~~122. ~~Plaintiff~~Plaintiffs and the Class members are reasonable consumers who expect device manufacturers and medical service providers like Defendants to provide accurate and truthful representations regarding the safety and efficacy of their products. Further, reasonable consumers, like ~~Plaintiff~~Plaintiffs and the Class members, rely on the representations made by device manufacturers and medical service providers regarding the safety and efficacy of their medical devices in determining whether to purchase and consider that information important to their purchase decision.

~~99.~~123. Defendants profited from the sale of the falsely, deceptively, and unlawfully advertised device and procedure to consumers.

~~100.~~124. Defendants' wrongful business practices constituted, and constitute, a continuing course of conduct in violation of the CLRA.

~~101.~~125. ~~Plaintiff~~Plaintiffs and Class members have been harmed and have suffered actual damages in that they paid substantial amounts of money for the valueless Penuma device and implantation procedure.

~~102.~~126. As a direct and proximate result of Defendants' unfair and deceptive acts and practices, ~~Plaintiff~~Plaintiffs and the Class members have suffered and will continue to suffer actual damages.

~~103.~~127. Pursuant to CAL. CIV. CODE § 1780, ~~Plaintiff seeks~~Plaintiffs seek injunctive relief, his reasonable attorney fees and costs, and any other relief that the Court deems proper.

~~104.~~128. ~~Plaintiff has~~Plaintiffs have provided Defendants with notice of their alleged violations of the CLRA pursuant to CAL. CIV. CODE § 1782(a). Defendants failed to provide appropriate relief for their violations of the CLRA.

~~Plaintiff~~Plaintiffs therefore ~~is now amending his Complaint to~~ seek monetary, compensatory, and punitive damages, in addition to injunctive and equitable relief.

COUNT THREE – Violation of California's Unfair Competition Law, CAL. BUS. & PROF. CODE § 17200 *et seq.* ("UCL")

~~105.~~129. ~~Plaintiff incorporates~~Plaintiffs incorporate by reference all of the foregoing allegations as if they were fully set forth here.

~~106.~~130. ~~Plaintiff brings~~ Plaintiffs bring this claim individually and on behalf of the Class against all Defendants.

~~107.~~131. The UCL prohibits acts of unfair competition, including any "unlawful, unfair or fraudulent business act or practice" and "unfair, deceptive, untrue or misleading advertising." CAL. BUS. & PROF. CODE § 17200.

~~108.~~132. The UCL applies to Defendants' advertisements because the marketing decisions that that led to the false and misleading advertising were made in California.

~~109.~~133. Defendants' business acts and practices alleged herein are unlawful in that they violate:

(a) The False Advertising Law, CAL. BUS. & PROF. CODE §§ 17500 *et seq*.

(b) The Consumer Legal Remedies Act, CAL. CIV. CODE §§ 1750 *et seq*.;

(c) The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq*.; and

(d) The California Sherman Food, Drug, and Cosmetic Law, CAL. HEALTH & SAFETY CODE §§ 110100 et seq.

~~110.~~134. Defendants' conduct alleged herein was also unfair because this conduct is immoral, unethical, unscrupulous, and substantially injurious to

consumers. The utility of Defendants' conduct is non-existent and does not outweigh the gravity of the harm to ~~Plaintiff~~Plaintiffs and the Class members.

~~111.~~135. Defendants' conduct is also unfair because it violates public policy as declared by specific statutory and regulatory provisions, including but not limited to the applicable sections of the False Advertising Law, the Consumer Legal Remedies Act, the federal Food, Drug, and Cosmetic Act, and the California Sherman Food, Drug, and Cosmetic Law.

~~112.~~136. Defendants' conduct alleged herein was also fraudulent because an objective, reasonable consumer is likely to be misled by Defendants' claims to believe that Penuma is safe and effective and that its FDA-~~cleared for cosmetic enhancement~~clearance denotes official approval of ~~normal penises~~the device in some way, as well as that the procedure is permanent ~~and~~but reversible.

~~113.~~137. Defendants profited from their sale of the falsely, deceptively, and unlawfully advertised device and procedure to consumers.

~~114.~~138. ~~Plaintiff~~Plaintiffs and the Class members are likely to continue to be damaged by Defendants' deceptive trade practices, because if the Penuma device and procedure were redesigned to be safe and effective for cosmetic penile enlargement~~, FDA-cleared for this use,~~ and truthfully marketed, there is a possibility that ~~Plaintiff~~Plaintiffs and the Class members would purchase a Penuma device and procedure in the future. Thus, injunctive relief enjoining Defendants' false and misleading advertising is proper.

~~115.~~139. Defendants' conduct has caused and continues to cause substantial injuries in fact to ~~Plaintiff~~Plaintiffs and Class members. As a result of their reliance on Defendants' misrepresentations and omissions, ~~Plaintiff~~Plaintiffs and the Class members suffered ascertainable losses of money and property—

namely the money they paid for the valueless Penuma device and implantation procedure.

~~116.~~140. In accordance with CAL. BUS. & PROF. CODE § 17203, ~~Plaintiff seeks~~Plaintiffs seek an order enjoining Defendant from continuing to conduct business through unlawful, unfair, and/or fraudulent acts and practices.

~~117.~~141. ~~Plaintiff~~Plaintiffs, on behalf of the Class, also seeks an order for restitution of all monies from the sale of the Penuma device and implantation procedure, which were unjustly acquired through acts of unlawful competition.

VIII. CONCLUSION AND PRAYER

WHEREFORE, ~~Plaintiff~~Plaintiffs, individually and on behalf of the Class, respectfully ~~requests~~request that the Court enter judgment ordering relief as follows:

(a) certifying the Class pursuant to FED. R. CIV. P. 23(b)(3) and/or (b)(2);

(b) appointing ~~Plaintiff~~Plaintiffs to represent the Class;

(c) appointing ~~Plaintiff's~~Plaintiffs' counsel as Class Counsel;

(d) enjoining Defendants from further deceptive advertising, marketing, and other false and misleading business practices with respect to their representations regarding the Penuma device and procedure;

(e) enjoining Defendants to cease and desist stating that Penuma is "FDA-cleared for cosmetic enhancement" on their websites and in advertisements and other marketing materials without disclosing that it is ~~cleared for use only for "use in the cosmetic correction of soft tissue deformities."~~not tested or approved by the FDA;

(f) awarding ~~Plaintiff~~Plaintiffs and the Class members restitution in an amount to be proven at trial;

(g) awarding ~~Plaintiff~~Plaintiffs and the Class members reasonable attorneys' fees, expenses, and costs of suit pursuant to CAL. CODE CIV. P. § 1021.5;

(h) awarding pre-judgment and post-judgment interest, as provided by law;

(i) granting leave to amend the Complaint to conform to the evidence produced at trial; and

(j) awarding such other relief as this Court may deem just and proper.

IX. DEMAND FOR JURY TRIAL

~~Plaintiff~~Plaintiffs hereby ~~demands~~demand a trial by jury on all issues so triable.

Dated: ~~January 20, 2023~~July 19, 2023

Respectfully submitted,

By: */s/ Michael A. Caddell*

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